Exhibit E

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO CAROLYN LEWIS, ET AL. v. ETHICON, INC. Case No. 2:12-CV-04301	Joseph R. Goodwin U.S. District Judge

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NOVEMBER 12, 2013

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Deposition of PEGGY PENCE, Ph.D., RAC, FRAPS, VOLUME I, held at Hyatt Westlake Village, 880 South Westlake Boulevard, Westlake Village, California, beginning at 9:10 a.m., on the above date, before Kimberly S. Thrall, a Registered Professional Reporter and Certified Shorthand Reporter.

Golkow Technologies, Inc.

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Ethicon.

Q. Okay. So these were MDR issue reports?

A. They're complaints.

Q. Complaints?

A. Yeah. They're -- the issue report is the document on which Ethicon records complaints and its investigation of complaints and whether or not they are reportable to governmental agencies, FDA or in the case of Europe, for example, the European authorities.

Q. On page 98, I think you say there were 862 TVT issue reports received and reviewed for this report?

A. Yes.

Q. Okay. 258 were determined not to be reportable?

A. Yes. Approximately 30 percent of those that we received were not reportable, according to Ethicon.

Q. Exhibit 3 has 29 AEs that were not reported?

A. Yes. Those are, as I said, examples.

Q. Does Exhibit 3 contain all of the issue reports that you believe Ethicon should have reported to the FDA for a serious injury definition?

A. It's not -- it's not a comprehensive compilation. It's representative examples.

Q. Do you have the other ones that you -- let me ask you this: Do you intend to come to trial and say

A. So that's why I'm saying I'd have to go back and look at every MDR for any mesh product to see if FDA knew about it before or not, if we're talking about specific -- any specific adverse event, if I understand your question correctly.

Q. You did.

With regard to the TVT issue reports that you believe were not submitted --

A. But should have been.

Q. -- but should have been, I mean, that's a given in the question. Let me just redo the question, then.

With regard to the TVT issue reports that you believe were not -- strike that. I see. You corrected me.

With regard to the TVT issue reports which you believe should have been reported, okay, do they impact the overall risk/benefit analysis of the TVT device?

MR. KUNTZ: Objection.

THE WITNESS: There are a couple of points to be made with regard to that. The regulation requires that all adverse events that made a certain definition be reported to the FDA. The purpose of that is so that the FDA can have a complete picture and if -- of the true safety profile of products. We already know there's underreporting. And in this case, there's

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NOVEMBER 13, 2013

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Deposition of PEGGY PENCE, Ph.D., RAC, FRAPS, VOLUME II, held at Hyatt Westlake Village, 880 South Westlake Boulevard, Westlake Village, California, beginning at 10:16 a.m., on the above date, before Kimberly S. Thrall, a Registered Professional Reporter and Certified Shorthand Reporter.

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Let me ask you this: With regard to medical devices, have you ever had to review adverse event data and make determinations whether MDR reports should be submitted to the FDA?

A. Yes.

Q. Okay. And when did you have that experience?

A. As recently as within the last year.

Q. Did your experience in reviewing MDR reports ever include surgical mesh?

A. No. But the same principles apply.

Q. Did your experience ever involve reviewing adverse event data on a device used to treat stress urinary incontinence?

A. No.

Q. Did you individually look at medical information, including the MDR report and any follow-up information you may have seen, and then make your own medical judgment based on your review of the matter whether the MDR should be submitted to the FDA?

A. I think I understood that question, but it was lengthy. Could I just have you repeat it back, please.

MR. SNELL: I'll ask the court reporter to, if that's okay with you.

THE COURT REPORTER: Of course.

(The following record was read by the reporter:

"Q. Did you individually look at medical information, including the MDR report and any follow-up information you may have seen, and then make your own medical judgment based on your review of the matter whether the MDR should be submitted to the FDA?")

THE WITNESS: Let me just clarify a little bit of the language. The MDR reports and maybe -- let me ask you, do you mean the issue reports instead of MDR reports? Because MDR reports would have already been submitted to the FDA.

BY MR. SNELL:

Q. I'm sorry. The issue reports.

A. Issue reports. Okay.

So, yes, as we discussed yesterday, the issue reports, I have reviewed issue reports which were not reportable and, in fact, you know, as we talked about yesterday, I have examples in my report and the exhibits attached to my report of issue reports that I did review and based on my review of those issue reports determined that they should have been reported to the FDA as MDR reports.

Q. You're not a doctor or a surgeon, so you didn't exercise medical judgment, did you?

A. I exercised -- if you look at the regulations

and you look at the types of individuals that FDA considers qualified to review issue reports and determine -- or complaints and determine whether or not they qualify as MDR reports, that includes not only physicians, but nurses, risk managers and biomedical engineers. I have functioned in the capacity of a risk manager for review of medical -- of adverse event reports for years and years of my career and I applied in making my determinations of the reportability of these issue reports that we've -- that we discussed yesterday.

And the ones that are in my report, I applied the same standard of practice that I do on a daily basis in execution of my responsibilities for the clients with whom I work.

Q. But you didn't use medical judgment, did you?

MR. FREESE: Object to the form of the question.

THE WITNESS: You don't have to be --

BY MR. SNELL:

Q. I'm sorry. It's a yes-or-no question.

MR. FREESE: Object to the form of the question anyway.

THE WITNESS: I used my -- my medical knowledge as a toxicologist and a clinical development regulatory

scientist and applied that in the context of the regulations. I'm not a doctor. So in that sense, I didn't apply a physician's knowledge, but I applied the knowledge in the fashion that I mentioned.

BY MR. SNELL:

Q. Have you reviewed any of the attorney advertising that pertains to TVT in connection with your expert report?

A. Attorney advertising?

Q. Yes.

A. No.

Q. Did you ever ask counsel for any of the Lewis case-specific materials, such as her medical records and her depositions?

A. No, I did not. I did ask the date of the surgery and, you know, general information, but not for specific records.

MR. SNELL: Let's go off the record for a second.

(Brief recess.)

MR. SNELL: Let's go back on.

BY MR. SNELL:

Q. You looked at the IFU for TVT, correct?

A. Yes.

Q. Okay.

A. Multiple IFUs.

Q. Right. Did you look at the IFUs across all other products to treat incontinence or prolapse that are mesh products?

A. Across other manufacturers' --

Q. Yeah. I --

A. -- products? Certainly, as we talked yesterday -- are you talking about SUI or are you talking about POP?

Q. Well, we can start with SUI. So what other IFUs for SUI products, if any, have you looked at?

A. I'm in the process of looking at some others at the moment for SUI, but --

Q. The one you identified yesterday was the Obtryx, Boston Scientific?

A. Boston Scientific, yes.

Q. And what about for prolapse meshes? Have you looked at other manufacturers' IFUs, you know, like you did with TVT across time in the different versions?

A. For the Bard Avaulta product.

Q. And I think your report identifies that there are 80 or 90 mesh products in total that have been 510(k) cleared?

A. That's not the number of mesh products. I'm sorry. That's the number of clearances, if I recall